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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/929,371	08/13/2001	Fred H. Burbank	9619-1001	2284

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EXAMINER

SZMAL, BRIAN SCOTT.

ART UNIT	PAPER NUMBER
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3736

DATE MAILED: 10/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/929,371

Applicant(s)

BURBANK ET AL.

Examiner

Brian Szmal

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 August 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 17-25, 27, 28, 30, 32, 33 and 40-69 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 17-25, 27, 30, 32 and 40-69 is/are rejected.
- 7) ☒ Claim(s) 28 and 33 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All. b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 6/22/06; 7/13/06; 8/23/06.

- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 17-23, 25, 27, 30, 32, 48-58 are rejected under 35 U.S.C. 102(e) as being anticipated by Patterson et al (5,941,869).

Patterson et al disclose a means for removal of stenotic material and further disclose an elongated shaft, a longitudinal axis; an electrosurgical cutting element on a distal portion of the shaft which is configured to receive RF energy from a source thereof for severing a specimen by rotating about the longitudinal axis to create a peripheral boundary about the tissue specimen, at least one encapsulating element that is secured to the distal portion of the shaft which is configured to encapsulate the severed specimen as the elongated shaft is rotated about the longitudinal axis, so that the severed specimen can be withdrawn from the patient's body; the encapsulating element comprises a band or a plurality of bands which is/are actuatable between a retracted position and an extended position; the electrosurgical cutting element comprises one of the encapsulating elements; the electrosurgical cutting element is axially aligned and actuatable between a retracted position and an extended position, and rotatable about the axis in the extended position to isolate the specimen from the surrounding tissue at the target site

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by defining a peripheral margin about the specimen; a sheath that is axially movable between the distal and proximal positions for selectively covering and uncovering the encapsulating element; the tubular member is formed of a polymeric material; advancing the instrument to the target site; radially expanding the electrosurgical cutting element away from the elongated shaft; rotating the radially extended arcuate shaped electrosurgical cutting element to cut a specimen for the surrounding tissue; encapsulating the specimen as the extended cutting element is rotated about the axis; removing the encapsulated specimen and instrument from the body; and an RF electrosurgical cutting element. See Figures 2, 3, 7, 11, 12, 33-39; Column 13, lines 2-15 and 46-60; Column 18, lines 64-67; Column 19, lines 1-7; and Column 27, lines 4-49.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 24 and 59 are rejected under 35 U.S.C. 103(a) as being unpatentable over Patterson et al (5,941,869) as applied to claims 23 and 57 above, and further in view of Kieturakis (5,794,626).

Patterson et al, as discussed above, disclose a means for removing matter from the body, but fail to disclose twisting the bands of the encapsulating assembly to encapsulate the specimen.

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Kieturakis discloses an excisional stereotactic device and further discloses twisting the bands of the encapsulating assembly to encapsulate the specimen. See Figure 14; and Column 9, lines 6-10.

Since both Patterson et al and Kieturakis disclose means for removing matter from the body, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the means of Patterson et al to include rotation of the encapsulating elements to encapsulate the matter, as per the teachings of Kieturakis, since it would provide a means of ensnaring the severed matter and ensuring the severed matter is removed from the target site.

Allowable Subject Matter

5. Claims 28 and 33 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Response to Arguments

6. Applicant's arguments filed January 3, 2006 have been fully considered but they are not persuasive.

The Applicants argue Patterson et al (5,941,869) disclose the use of electrical energy to assist in the removal of the tissue, but fails to disclose the use of RF energy to form a peripheral boundary around the tissue specimen prior to removing the tissue specimen. The Examiner respectfully traverses this argument, because the disclosure

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of electrical energy, within the electrosurgical art, broadly encompasses RF energy as well as microwave energy. Patterson et al also clearly discloses the forming of a peripheral boundary around the tissue specimen prior to removal, as can be seen in Figures 34-39. As the expandable elements are expanded towards the stent, they reach an outer periphery as defined by the stent and then the elements are rotated about this periphery to sever the tissue specimen from the surrounding tissue, thereby creating a peripheral boundary about the tissue specimen prior to removal.

Therefore, Patterson et al still anticipate the current claims and the previous rejection stands.

Conclusion

7. This is an RCE of applicant's earlier Application No. 09/929,371. All claims are drawn to the same invention claimed in the earlier application and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the earlier application. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action in this case. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

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extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no, however, event will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Szmaj whose telephone number is (571) 272-4733. The examiner can normally be reached on Monday-Thursday, with Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



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